

REMARKS/ARGUMENTS

By the foregoing amendment, claims 1, 21, 22 and 25 have been amended to clarify the claimed subject matter. Specifically, Claims 1 and 25 have been amended to further recite that the right and left foot members extend angularly from the distal end of the elongate member and to one side of the elongate member. Support for these amendments to claims 1 and 25 can be found in Figures 1, 2, 3, 4, 4A and 5 of the present specification. Claims 21 and 22 have been amended to depend from Claim 20. No new matter has been added. A Request for Continuing Examination (RCE) is filed herewith. Following entry of this amendment, claims 1, 6-25 and 27-40 will be pending. Reconsideration is requested.

Claim Objections

In the Office Action, claims 21 and 22 were objected to on the basis of insufficient antecedent basis for the element “cannula”. By the forgoing amendment, claims 21 and 22 have been amended to overcome these stated objections. Reconsideration is therefore requested.

35 U.S.C. §102(b) Rejections

Claims 1, 6-9, 11, 14-19, 25 and 27 have been rejected under 35 U.S.C. §102(b) as being anticipated by United States Patent 6,068,629 (Haissaguerre et al.) Applicant traverses this rejection for the following reasons.

In order to anticipate a claim, a single prior art reference must disclose each and every feature of the anticipated claim. *In re Spada*, 911 F. 2d 705, 708; 15 U.S.P.Q. 2d 1655, 1657 (Fed. Cir. 1990). That is, anticipation requires exact identity between the prior art and the claimed invention such that the disclosure of the prior art establishes that the claimed invention existed identically before the invention thereof by the applicant. In addition, the reference must be enabling and describe the applicant’s claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention. *In re Spada*, *id.*

A non-limiting example of the presently claimed invention is shown in Applicant's Figures 2, 4 and 5, reproduced below:

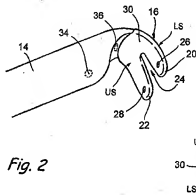


Fig. 2

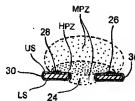


Fig. 5

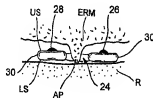


Fig. 4A

As the Examiner will note with respect to the examples of Figures 2, 4A and 5, the claimed invention provides a device that has a right foot member (22), a left foot member (20) that extend angularly from the distal end of the elongate member (14) and to one side of the elongate member with an open space (24) between the right and left foot members (20, 22). An insulating covering is located on at least the lower surfaces (LS) of the foot members (20, 22). Electrodes (26, 28) are located on the upper surfaces (US) of the foot members (20, 22). These electrodes are useable to create an electromagnetic field that thermally cuts or coagulates tissue located above the open space (24) while not causing substantial thermal cutting and/or coagulation of tissue that is located below the lower surfaces (LS) of the right and left foot members (20, 22). The tissue may protrude downwardly from an anatomical structure located above the foot members (as shown in the example of Figure 4A) or it may protrude upwardly between the foot members (as described elsewhere in the specification).

As presently amended, independent device claim 1 recites a device that comprises:

an elongate member having a distal end;

a right foot member having an upper surface and a lower surface and a left foot member having an upper surface and a lower surface, the right and left foot members extending angularly from the distal end of the elongate member and to one side of the elongate member such that an open space exists between the right and left foot members;

an electrically and thermally insulating covering formed on at least the lower surfaces of the right and left foot members; and

an electrode on the upper surface of the right foot member; and

an electrode on the upper surface of the left foot member;

wherein the electrodes are energizable to thermally cut or coagulate tissue located above the open space located between the right and left foot members without causing substantial thermal cutting and/or coagulation of tissue located below the lower surfaces of the right and left foot members.

Also, as presently amended, independent method claim 25 recites a method for selective electrosurgical cutting or coagulation of tissue comprising the steps of:

A) *inserting a device which comprises;*

an elongate member having a distal end;

a right foot member having an upper surface and a lower surface and a left foot member having an upper surface and a lower surface, the right and left foot members extending angularly from the distal end of the elongate member and to one side of the elongate member such that an open space exists between the right and left foot member;

an electrode on the upper surface of the right foot member;

an electrode on the upper surface of the left foot member; and

an electrically and thermally insulating covering formed on at least the lower surfaces of the right and left foot members;

B) *positioning the device such that a mass of tissue that is to be cut or coagulated protrudes into an area located above the open space between the right and left foot members; and*

C) *energizing the electrodes to thermally cut or coagulate the mass of tissue above the open space located between the right and left foot*

members without causing substantial thermal cutting and/or coagulation of tissue located below the lower surfaces of the right and left foot members.

Independent claims 1 and 25 are patentably distinguishable over the cited Haissaguerre et al. on a number of grounds as described below.

For example, Haissaguerre et al. does not disclose any device or method comprising an elongate member having a distal end and, a right foot member having an upper surface and a lower surface and a left foot member having an upper surface and a lower surface wherein the right and left foot members extend angularly from the distal end of the elongate member and to one side of the elongate member. On the contrary, arms 34 and 36 or 108 and 110 of Haissaguerre et al. extend in diametrically opposite directions on different sides of shaft 6 (Fig. 1, 19A, 19B, 20) and cannot extend to one same side of shaft 6. Haissaguerre et al. discloses and teaches that when the distal ablation segment has a split tip configuration comprising first and second arm segments pivotally coupled to a hinge assembly at the distal end of the catheter shaft, the arms are pivotable about the hinge assembly in a collapsed configuration, where the arm segments are folded together and generally parallel to the shaft axis and, an expanded configuration, where the arms are split apart to form a continuous surface transverse to the shaft axis (see Column 3, line 65-Column 4, line 14). The arms in the expanded configuration cannot, therefore, extend angularly from the distal end of the shaft and to one side of the shaft axis.

Haissaguerre et al. does not disclose any device or method wherein right and left foot members having an electrically and thermally insulative coating on their lower surfaces and electrodes on their upper surfaces and an open space formed therebetween are positioned such that a mass of tissue resides above the open space. On the contrary, in Haissaguerre et al. the mass of tissue to be treated is in contact with the entire length of the ablation segment, that is adjacent the target site (see for example, Column 3, lines 22-26; Column 3, line 43 to Column 4, line 18; and Column 5, lines 35-37).

Haissaguerre et al. does not disclose any device or method wherein the electrodes of such a device are energized to thermally cut or coagulate the mass of tissue above the open space located between the right and left foot members without causing substantial thermal cutting

and/or coagulation of tissue located below the lower surfaces of the right and left foot members. On the contrary, Haissaguerre et al. discloses that the energized electrodes treat tissue that is in contact with the entire length of the ablation segment(s) so that a continuous linear lesion may be formed on the tissue (see for example, Column 3, lines 22-26; Column 3, line 43 to Column 4, line 18; and Column 5, lines 35-37).

Applicants submit that the present independent claims 1 and 25 are not anticipated by the Haissaguerre et al. reference for at least the reasons stated above and possibly other reasons not specifically articulated in these remarks. The remaining claims depend directly or indirectly from either claim 1 or claim 25 and, thus, are novel for at least the same reasons as stated above with respect to independent claims 1 and 25.

35 U.S.C. §103(a) Rejections

In the Office Action, claims 16-19 have been rejected under 35 U.S.C. §103 as being unpatentable over Haissaguerre et al. In addition, each of claims 10, 12, 13 and 2-29 were rejected under 35 U.S.C. §103 as being obvious over Haissaguerre et al. in view of United States Patent Application Publication No. 2002/0002372 (hereinafter Jahns et al.) Furthermore, Claims 20-24 and 40 have been rejected as being unpatentable over Haissaguerre et al. in view of United States Patent No. 6,283,961 (hereinafter Underwood et al.).

As presently amended, all claims are believed to be patentably distinguishable over Haissaguerre et al., Underwood et al. and Jahns et al. alone or in combination for the reasons stated below.

In the recent United States Supreme Court case *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 82 U.S.P.Q.2d 1385 (2007), Justice Kennedy affirmed that *Graham v. John Deere*, 383 U.S. 1, 36 (1966) continues to set forth the proper analytical test for obviousness. Pursuant to *Graham*, in an obviousness analysis, “the scope and content of the prior art [at the priority date of the application in question] are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.” 383 U.S. at 17, 148 U.S.P.Q. at 467. When “a person having ordinary skill in the prior art . . . would

immediately see that the thing to do was what" the inventor did, the invention is obvious. *Graham*, 383 U.S. at 24, 148 U.S.P.Q. at 469 (emphasis added).

As discussed above, the present independent claims 1 and 25, and therefore the claims depending therefrom, are novel over Haissaguerre et al. In addition, Haissaguerre does not teach or suggest the present invention. As mentioned above, Haissaguerre et al. does not disclose any device or method comprising an elongate member having a distal end and, a right foot member having an upper surface and a lower surface and a left foot member having an upper surface and a lower surface wherein the right and left foot members extend angularly from the distal end of the elongate member and to one side of the elongate member. On the contrary, arms 34 and 36 or 108 and 110 of Haissaguerre et al. extend to different sides of shaft 6 (Fig. 1, 19A, 19B, 20; reproduced below) and cannot extend angularly to the one side of shaft 6. Haissaguerre et al. discloses and teaches that when the distal ablation segment has a split tip configuration comprising first and second arm segments pivotally coupled to a hinge assembly at the distal end of the catheter shaft, the arms are pivotable about the hinge assembly in a collapsed configuration, where the arm segments are folded together and generally parallel to the shaft axis and, an expanded configuration, where the arms are split apart to form a continuous surface transverse to the shaft axis (see Column 3, line 65-Column 4, line 14). The arms in the expanded configuration cannot therefore extend angularly from the distal end of the shaft and to one side of the shaft axis.

Since the arms 34 and 36 or 108 and 110 cannot extend to the same side of shaft 6, Haissaguerre not only does not disclose the present device of Claim 1 or the method using the device of Claim 25, but in actual fact, teaches away from the presently claimed device or method of independent Claims 1 and 25 wherein the right and left foot members extend angularly in the from the distal end of the elongate member and to one side of the elongate member.

In addition, Haissaguerre et al. discloses that the energized electrodes treat tissue that is in contact with the entire ablation segments 108 and 110 so that a continuous linear lesion may be formed on the tissue (see for example, Column 3, lines 22-26; Column 3, line 43 to Column 4, line 18; and Column 5, lines 35-37) which teaches away from the device or method of the presently claimed invention wherein the right and left foot members have an open space formed therebetween and are positioned such that a mass of tissue resides above the open space so that

when the electrodes of such a device are energized, they thermally cut or coagulate the mass of tissue above the open space located between the right and left foot members without causing substantial thermal cutting and/or coagulation of tissue located below the lower surfaces of the right and left foot members.

Applicants submit therefore, that Haissaguerre et al. does not render obvious the device or method of independent Claims 1 and 25 of the present invention, much less dependent claims 16-19.

Jahns et al. describes suction stabilized epicardial ablation devices.

Jahns et al. does not disclose, teach or suggest the present device or method of independent Claims 1 and 25. Jahns et al. clearly does not describe or suggest any structure having right and left foot members extending angularly from the distal end of an elongate member and to one side of the elongate member with an open space between right and left foot members, an electrically and thermally insulative covering on at least the lower surfaces of the foot members and electrodes on the upper surfaces of the foot members. Furthermore, Jahns et al. fails to describe or suggest any method wherein such a device is used to thermally cut or coagulate the mass of tissue that is located above the open space between the right and left foot members without causing substantial thermal cutting and/or coagulation of tissue located below the lower surfaces of the right and left foot members.

As described above, Haissaguerre et al. not only does not disclose, teach or suggest the present invention, but in actual fact teaches away the present invention. Jahns et al. does not cure the deficiencies in the teachings of Haissaguerre et al. In addition, there is no motivation, teaching or suggestion either in Jahns et al. or Haissaguerre et al. to combine the teachings to arrive at the present device or method of independent Claims 1 and 25, much less the devices and methods of dependent claims 10, 12, 13 and 28-39.

Underwood et al. does not disclose, teach or suggest the device or methods of independent Claims 1 and 25 of the present application. Underwood et al. does not describe or suggest any device that has right and left foot members extending angularly from the distal end of an elongate member and to one side of the elongate member with an open space between the right and left foot members, an electrically and thermally insulative covering on at least the lower

surfaces of the right and left foot members and electrodes on the upper surfaces of the right and left foot members. Moreover, failing to describe or suggest these claimed elements of the device, it is axiomatic that Underwood et al. cannot describe or suggest any method wherein such a device is used to thermally cut or coagulate the mass of tissue that is located above the open space between the right and left foot members without causing substantial thermal cutting and/or coagulation of tissue located below the lower surfaces of the right and left foot members.

As described above, Haissaguerre et al. not only does not disclose, teach or suggest the present invention, but in actual fact teaches away the present invention. Underwood et al. does not cure the deficiencies in the teachings of Haissaguerre et al. In addition, there is no motivation, teaching or suggestion either in Underwood et al. or Haissaguerre et al. to combine the teachings to arrive at the present device or method of independent Claims 1 and 25, much less the devices and methods of dependent claims 20-24 and 40.

Accordingly, independent claims 1 and 25 are novel and unobvious over the cited Haissaguerre et al., Jahns et al. and Underwood et al. references for at least the reasons stated above and possibly other reasons not specifically articulated in these remarks. The remaining claims depend directly or indirectly from either claim 1 or claim 25 and, thus, are novel and unobvious for at least the same reasons as stated above with respect to independent claims 1 and 25.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and issuance of a notice of allowance is earnestly solicited. The Commissioner is hereby authorized to deduct the fee for the accompanying RCE as well as any other fee properly deemed to be due in connection with the filing of this response from Deposit Account No. 50-0878.

If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, the Examiner is encouraged to telephone the undersigned.

Respectfully submitted,

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